

REMARKS

Claims 20-30 and 36 are pending. Claims 21, 28-36 are cancelled, without prejudice. Claim 20 is amended. Support for this amendment can be found, e.g., in Claim 21 as previously filed. New Claims 37-41 are added. Support for new Claims 37-41 can be found in originally filed Claims 28-31 and 36. Applicants note that there were two claims numbered "Claim 28" in the previously filed claims. New Claims 37-41 rectify this problem. The Specification is amended to reflect the status of the parent application and to correct spelling errors as requested by the Examiner.

Applicants believe that no new matter is added by way of amendment.

I. Objections to the Specification.

The Examiner requested that the parent application status be updated. Applicants have amended the specification to describe the current status of the parent application. The Examiner further requested that any spelling errors be corrected, in particular, the spelling of the word naive. Applicants wish to point out that both "naive" and "naïve" are accepted means of spelling this particular word. In fact Applicants' spelling correction program automatically changes naive to naïve. Furthermore, Applicants bring to the Examiner's attention, the preliminary amendment filed on October 14, 2003, which already corrected several typographical errors. For the convenience of the Examiner, Applicants have amended the specification as requested again.

In view of the foregoing amendment, Applicants respectfully request withdrawal of the objections to the Specification.

II. References

Applicants note that the Examiner is unable to locate the references submitted in an Information Disclosure Statement in the parent application. Per the Examiner's request, courtesy copies of these references accompany this response.

III. Rejection of Claim 21 under 35 §112, Second Paragraph.

The Examiner rejected Claim 21 under 35 U.S.C. §112, second paragraph. The Examiner alleges that Claim 21 is indefinite for reciting "anti-CD3 and anti-CD28". Claim 21 is cancelled and the rejection is therefore moot as to this claim. Applicants have incorporated the Examiner's suggestion of "anti-CD3 antibody and anti-CD28 antibody" into currently amended Claim 20.

In view of the forgoing, Applicants submit that the rejection of Claim 21 under 35 U.S.C. §112, second paragraph, is overcome and as such, withdrawal of this rejection is respectfully requested.

IV. Rejections of Claims 20-30 and 36 under Obviousness-type Double Patenting.

The Examiner rejected Claims 20-30 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent 6,670,146 ('146) in view of US Patent 5,858,358 ('358). Claims 21, 28-31, and 36 are cancelled, and the rejection is therefore moot as to this claim.

The '146 patent claims a method of obtaining regulatory T cells comprising contacting naive CD34+ T cells with a stimulatory signal and combination of vitamin D3 and dexamethasone, wherein the regulatory T cell produces essentially only IL-10. The Examiner states that the '146 patent "... does not explicitly recite a method of obtaining regulatory T cells, wherein the stimulatory signal comprises anti-CD3 antibody and anti-CD28 antibody.". As amended, Claim 20, recites anti-CD3 antibody and anti-CD28 antibody. Thus, Applicants submit that the '146 patent does render the present invention obvious.

The '358 patent teaches a method of stimulating and proliferating CD4+ cells with anti-CD3 and anti-CD28 antibodies. This patent, however, does not teach contacting a naive CD4+ T cell with Vitamin D3, Dexamethasone, anti-CD3 antibodies, and anti-CD28 antibodies to produce a population of regulatory T cells that produce essentially only IL-10. The '358 patent teaches away from the present invention in that the anti-CD3 and anti-CD28 antibodies are used to stimulate the immune response. The present invention is directed to producing T cells that suppress the immune response. Applicants submit that the '358 patent does not render amended claim 20 and dependent claims 37-41 obvious, alone or in combination with the '146 patent.

Thus Applicants submit that a terminal disclaimer is not necessary to obviate this rejection.

In view of the forgoing, Applicants believe that the rejection of Claims 20-30 and 36 under the judicially created doctrine of obviousness-type double patenting, is overcome. Withdrawal of this rejection is respectfully requested.

Conclusion

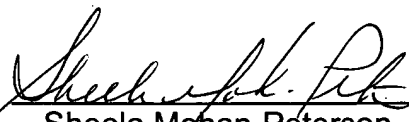
Applicants' current response is believed to be a complete reply to all the outstanding issues of the latest Office action. Further, the present response is a bona fide effort to place the application in condition for allowance or in better form for appeal. Accordingly, Applicants respectfully request reconsideration and passage of the amended claims to allowance at the earliest possible convenience.

Applicant believes that no additional fees are due with this communication. Should this not be the case, the Commissioner is hereby authorized to debit any charges or refund any overpayments to DNAX Deposit Account No. 04-1239.

If the Examiner believes that a telephonic conference would aid the prosecution of this case in any way, please call the undersigned.

Respectfully submitted,

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